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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,383	01/14/2002	Louis Michael Crowe	660057-2010	5507

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT PAPER NUMBER

3762

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/047,383

Applicant(s)

CROWE ET AL.

Examiner

George R Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-132 is/are pending in the application.
- 4a) Of the above claim(s) 11-14, 30-41, 45-55, 58-66, 77-80, 96-107, 111-121, and 124-132 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 15-29, 42-44, 56, 57, 67-76, 81-95, 108-110, 122, 123 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/4, 10/9, 1/14.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of the election of species in the reply filed on 1/10/05 is acknowledged. The traversal is on the ground(s) that the inventions are not independent or distinct and that there is not an undue burden on the examiner. This is not found persuasive because the inventions are independent and distinct. For example, the first embodiment of delivering a single pulse or a plurality of pulses is distinct since one embodiment does not depend on the other, since both embodiments can not be used at the same time, and/or since independent claims are presented for each embodiment. In addition, the argument that there is no undue burden on the examiner is not persuasive since the examiner must search different areas for the different embodiments and since each claim limitation of one embodiment is different than another embodiment and therefore the different claim limitations must be considered differently. For example, the single pulse embodiment will be searched in 607/72, whereas the plurality of pulses embodiment will be searched in 607/72.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-14, 30-41, 45-55, 58-66, 77-80, 96-107, 111-121, and 124-132 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected embodiments, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/10/05.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 4-7, 15, 24, 25, 43, 44, 81, 90, and 91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 4-7, 43, and 44, the claims are vague since they are not limiting the apparatus but are limiting the response of the patient. It is suggested to use functional language, such as “wherein the parameters are selected to burn calories in the muscles of the subject...”, to limit the apparatus.

In claims 15 and 81, “16C” should be “16nC”.

In claims 24, 25, 90, and 91, the claims are vague since they have not positively recited a claim limitation, but only recited a preference or possibility. It is suggested to state something similar to “wherein the effective contact area of the relevant electrode is at least 140 mm”.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 15-24, 26-29, and 42-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Minogue et al (WO 00/41764). Minogue states that his device is used to stimulate/contract the muscles (abstract and throughout the specification), uses electrodes sized from 80 to 120 mm by 50 to 150 mm (page 24) and delivers pulses using parameters of 50-1000 microseconds pulse duration, 1-200 Hz, and 0-100 mA (page 25) and pulses where the amplitudes are different (figure 18) and therefore is capable of meeting the functional use

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recitations in the claims of “so as to induce a shivering phenomenon” and generating a cardiovascular response greater than 50-70% since Minogue uses the exact same pulse parameters and electrode sizes as the applicant to cause the muscle to contract. Also, since the pulses are delivered through the same sized electrodes and contain the same pulse parameters, the charge delivered by the Minogue will be the same and meet the claimed charge limitations. In addition, it is noted that the applicant’s specification states on page 3, that the “shivering also encompasses all such muscle movements, irrespective of frequency or intensity, as long as designed to burn calories in a subject”.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 67-76, 81-90, 92-95, and 108-110 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Minogue et al.

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Minogue provides and uses the claimed pulse parameters and electrode sizes in the claimed ranges (as seen above) and therefore meets the claimed limitations.

In the alternative, Minogue discloses the claimed invention and that the pulses and electrodes can be varied to fit the patient (pages 24, 25, and 32) except for applying the pulses and electrodes at the specific ranges, such as from 4-8 Hz, 0.1 mA/mm², 140 mm, etc to maximize the stimulation of the bulk of the muscle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the muscle stimulation system and method as taught by Minogue, with the specific pulse and electrode parameters since it was known in the art that muscle stimulation systems and methods use those particular pulse parameters, such as 4-8 Hz, 0.1 mA/mm², 140 mm, etc., to effectively stimulate and contract the muscles for therapy. In addition, Minogue provides a clear suggestion that the pulse parameters and electrodes can be modified to vary the parameters and electrodes to fit the patient and muscle being stimulated. The determination of the most appropriate pulse parameters and electrode size by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the medical art.

Claims 25 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minogue et al. Minogue states on page 32 that electrodes can be used on different muscles such as leg muscles and discloses the electrode sizes can be varied on page 24, but does not disclose the length being 190 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrode size in the muscle stimulation system as taught by Minogue, with the length of the electrode being 190 mm since it was known in the art that muscle stimulation systems provide longer electrodes, such as being of the length of at least

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190 mm, to efficiently stimulate the longer muscles to cause them to contract without causing pain or burning due to the electrical pulse. In addition, Minogue provides a clear suggestion that the electrodes can be modified to vary electrodes to fit the patient and muscle being stimulated. The determination of the most appropriate electrode size by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the medical art.

Claims 56, 57, 122, and 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minogue et al. Minogue discloses the claimed invention except for the monitor for monitoring a physiological parameter such as heart rate and a feedback mechanism for controlling the signal generator based on the output of the monitor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system and method of stimulation as taught by Minogue, with a monitor for monitoring a physiological parameter such as heart rate and a feedback mechanism for controlling the signal generator based on the output of the monitor since it was known in the art that stimulation systems and methods use a monitor for monitoring a physiological parameter such as heart rate and a feedback mechanism for controlling the signal generator based on the output of the monitor to provide feedback to the signal generator to allow the stimulation to be applied within physiological limits and at a safe level to the patient so the patient does not overexert himself or go outside of the physiological limits.

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Petrofsky, Gliner, Reiss and Lieber are four examples of many teaching the use of a physiological feedback, such as heart rate, to control the stimulation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


George R Evanisko
Primary Examiner
Art Unit 3762

2/7/5

GRE
March 7, 2005